

REMARKS

Claims 1-42 and 44-52 are pending in the present application.

Claim 43 was previously canceled without prejudice or disclaimer. Claim 17 has been canceled by the present amendment without prejudice or disclaimer.

Claims 3-6, 11, 19, 21-42, 44-46, and 48-52 stand withdrawn from consideration. Claims 28 and 29 have been amended to be consistent with amendments to Claims 8 and 9, as described below.

Claims 1 and 18 have been amended to recite the phrase "at about 1-3 weeks prior to harvesting." Support is found at page 2 of the specification as filed, lines 17-20, which provides that "the tobacco plants are sprayed with the chemical solution in a single application or multiple applications about 1-3 weeks prior to harvest."

Claims 8 and 9 have been amended to clarify the subject matter claimed. Support for amending Claim 8 is found at page 4, lines 13-15, which states "to reduce the availability of carbon dioxide necessary for photosynthesis."

No new matter has been added. Reconsideration and allowance are respectfully requested in view of the following remarks.

Claim Objections

Claims 17 and 47 stand under objection for allegedly claiming the same subject matter. Claim 17 has been canceled without prejudice or disclaimer. Thus, Applicants respectfully request the withdrawal of the objection against Claim 47.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 7-10, 12-18, 20, and 47 stand rejected under 35 U.S.C. §112, first paragraph, for purportedly providing a disclosure that does not enable the full scope of the claims (see Official Action, at page 3, lines 1-6).

MPEP §2164.01 provides that in order to establish a *prima facie* case of nonenablement, the Examiner must provide a rational basis for asserting that a disclosure does not teach or for doubting the objective truth of the statements in the disclosure that purports to teach the manner/process of making and using the invention. The test of enablement is whether the scope of the disclosure corresponds to the scope of the claimed invention to enable a person skilled in the art to make and to use the claimed invention without undue experimentation as of the filing date of the application. Subject matter known to persons skilled in the pertinent technology need not be disclosed. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." "A patent need not teach, and preferably omits, what is well known in the art." *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicants traverse and assert that a *prima facie* case of nonenablement has not been established.

Independent Claim 1, as amended, recites: A method of reducing tobacco-specific nitrosamines in cured tobacco, comprising
 raising the levels of antioxidants in tobacco leaves by spraying a chemical solution onto the leaves of a growing tobacco plant at least one time prior to harvesting at about 1-3 weeks prior to harvesting,
 the antioxidants being raised at least 25 % compared to harvested tobacco plants grown without being sprayed with the chemical solution.

Applicants submit that the specification sufficiently describes the method recited in Claim 1, as amended, to enable persons skilled in the art to practice the full scope of Claims 1, 2, 7-10, 12-18, 20, and 47. The Official Action states that "while enabling for several chemical solutions (including ABA), [the disclosure] does not reasonably provide enablement for any or all chemical solutions ... Not all chemical solutions will lower the level of TSNA in tobacco with foliar spraying" (at page 3, lines 1-6). Applicants note that the method of Claim 1 recites "raising the levels of antioxidants in tobacco leaves by spraying a chemical solution onto leaves of a growing tobacco plant at least one time prior to harvesting ..., the antioxidants being raised at least 25 % compared to harvested tobacco plants grown without being sprayed with the chemical solution (emphasis added)," which does not leave the terms "chemical solutions" as open-ended as suggested by the Examiner. The **chemical solutions** that are suitable for the claimed method **for reducing tobacco-specific nitrosamines in cured tobacco have the capacity to raise the "levels of antioxidants in tobacco leaves" when sprayed onto such tobacco leaves in an amount sufficient to raise the levels of antioxidants to at least 25% compared to levels of antioxidants in tobacco plants not sprayed with the chemical solutions.** Dependent **Claim 7** recites "wherein the chemical solution contains a herbicide, a plant activator, plant growth hormone and/or stress inducing agent," which is directed to multiple combinations of subgenus of compounds that can be included in the vast number of possible "chemical solutions" contemplated in the disclosure.

Applicants submit that the specification sufficiently describes multiple examples of herbicides, plant activators, plant growth hormones, and/or stress inducing agents that have the capacity to increase the levels of antioxidants to at

least 25% compared to levels of antioxidants in tobacco plants not sprayed with the chemical solutions. For example, consider the following (references to the specification is made to specific paragraph numbers of the published application for convenience):

A) [0020] provides, under the definition of "**herbicide**," a list of reagents that increase antioxidant activity, including: redox-active herbicides such as diphenyl ethers (e.g., acifluorfen and acifluorfen sodium) and bipyridyl herbicides such as methyl viologen (e.g., Paraquat) and/or Diquat. Furthermore, [0033-34] provide additional examples of suitable herbicides. [0035] provides examples of spraying schedules relative to time of harvest. [0036] provides examples of concentration ranges of chemical solutions suitable for spraying mode of application.

B) [0021] provides, under the definition of "**plant growth hormone**," a list of reagents that modulate the antioxidant level and thereby TSNA in tobacco plants including: abscisic acid (ABA) and/ or jasmonic acid. Furthermore, [0041- 46] provide additional examples of suitable plant growth hormones, exemplary concentration ranges, and application schedules.

C) [0022] provides, under the definition of "**plant activator**," a list of reagents that modulate the antioxidant level and thereby TSNA in tobacco plants including: salicylic acid, or an analog of salicylic acid, (e.g., ACTIGARD®), and/ or a harpin protein (e.g., MESSENGER®). Furthermore, [0037- 40] provide additional examples of suitable plant activators, exemplary concentration ranges, and application schedules.

D) [0023] provides, under the definition of "**stress inducing reagents**," a list of reagents that modulate the antioxidant level and thereby TSNA in tobacco plants including: sulfur dioxide, sodium chloride, and/or hydrogen peroxide. Furthermore, [0047- 54] provide additional examples of suitable stress inducing reagents, exemplary concentration ranges, and application schedules.

E) Embodiments described in [0055- 61] are directed to combinations of reagents described above in A-D.

F) Example 1 and Table 1 provide comparative antioxidant capacities induced by salicylic acid and methyl viologen relative to the control (unsprayed).

G) Example 2 and Table 2 provide comparative antioxidant capacities induced by ACTIGARD® and MESSENGER® relative to the control (unsprayed).

H) Example 3 and Table 3 provide comparative antioxidant capacities induced by three concentrations of NaCl relative to the control (unsprayed).

Because the specification sufficiently describes how to make and how to use the "chemical solutions" recited in independent Claim 1, Applicants assert that a *prima facie* case of nonenablement has not been established. In view of the above discussion, Applicants respectfully request the withdrawal of the rejection of Claims 1, 2, 7-10, 12-17, and 47, and request the allowance of these claims.

Based on similar arguments presented for Claim 1 and dependent claims, Applicants request the withdrawal of the rejection of Claim 18, as amended, (directed to a method of reducing tobacco-specific nitrosamines in cured tobacco, wherein the chemical solution comprises an aqueous solution ...) and Claim 20 (directed to a cigarette comprising the cured tobacco of Claim 10).

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 7-10, 12 and 20 stand rejected under 35 U.S.C. §102(b) in view of *Kim et al.* (Korean Journal of Botany, vol. 29(1), pp. 41-51 (1986)) ("*Kim*").

MPEP §2131 provides that a claim is deemed anticipated "**only if each and every element** as set forth in the claim is found, either expressly or inherently described, in **a single prior art reference**" (emphasis added; MPEP quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 2USPQ2d 1051, 1053 (Fed. Cir. 1987)). Thus, a proper *prima facie* case of anticipation requires that a single reference, provided by an Examiner, discloses **each of the claimed elements** as interpreted by one of ordinary skill in the art.

With respect to Claim 1, the **Official Action** states that *Kim* discloses the claimed method because *Kim*'s "plants were respectively sprayed" with "15 ml of...100 µgrams ml⁻¹" as described under "Plant materials" of "Materials and Methods" section for "at least one time prior to harvesting" (page 42). "Since *Kim et al.* discloses spraying ABA at a concentration within those disclosed by Applicants at pages 9 and 10 of the specification, **the method of *Kim et al.* would inherently raise the antioxidant level at least 25%.**"

Applicants traverse and assert that a *prima facie* case of anticipation has not been established. Applicants assert that *Kim's* method does not disclose, explicitly or inherently, the steps as recited in Claim 1. *Kim's* method requires the spraying of ABA "once in every two days after germination ... After 12 weeks, the young and fully expanded second leaves from tip were harvested" for analysis" (emphasis added, page 42). Applicants note that **Germination** is the process by which growth of a shoot emerges from a period of dormancy. The most common example of germination is the sprouting of a seedling from a seed. Germination is the first stage in which a seedling is made.

In contrast to *Kim's* method, the **method for reducing tobacco-specific nitrosamines in cured tobacco** recited in Claim 1, as amended, comprises "raising the levels of antioxidants in tobacco leaves by spraying a chemical solution onto the leaves of a growing tobacco plant at least one time prior to harvesting at about 1-3 weeks prior to harvesting, the antioxidants being raised at least 25 % compared to harvested tobacco plants grown without being sprayed with the chemical solution" (emphasis added). Thus, the claimed method is applicable to a mature, non-germinating tobacco plant. Furthermore, *Kim's* method does not disclose the relationship between the spraying of ABA onto germinating leaves and decreasing the concentration of TSNA's in cured tobacco, as recited in the preamble of Claim 1.

Furthermore, the specification (see page 4, lines 7-26, or [0014] of the published application) states (emphasis added):

[0014] The amount of antioxidants in tobacco leaves during the time of air-curing is believed to be advantageous to the inhibition of TSNA formation. An elevated concentration of native antioxidants during senescence and air-curing of tobacco can be obtained by spraying of a chemical solution preferably comprising an aqueous solution containing one or more chemical

compounds onto the growing tobacco plant and/or treating the soil surrounding roots of growing tobacco plants with the aqueous solution. For example, it is possible to increase foliar contents of native antioxidants by stressing the tobacco plant, e.g., using ABA to reduce the availability of carbon dioxide necessary for photosynthesis. Preferably the tobacco is burley tobacco. The spraying of the solution and/or soil treatment preferably occurs between topping (i.e., removal of the flower from the tobacco plant to stimulate leaf production) and harvest, and is intended to stimulate the production of antioxidants and interfere with the formation TSNAs during curing of the tobacco. Preferably, the level of antioxidants is increased to an amount sufficient to prevent significant nitrosation during the yellowing and browning phases of curing. The chemical spraying and/or soil treatment can be carried out only once or the tobacco plants can be sprayed and/or subjected to soil treatment more than once. For example, the plants can be sprayed at layby (when the plants are about knee-high) and the spray treatment can be repeated periodically such as every 5 to 15 days until harvest. Likewise, the soil in which the plants are grown can be treated at layby and the soil treatment can be repeated periodically such as every 5 to 15 days until harvest.

Thus, Applicants submit that *Kim's* method does not explicitly disclose the recited steps of Claim 1.

Furthermore, in order to properly reject claims based on allegations of inherency of undisclosed steps, the **MPEP §2131** provides that "evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill" (emphasis added). Applicants assert that although *Kim* recognizes the relationship between the spraying of ABA and reduction in leaf length, plant height, chlorophyll content, protein content, stomatal frequency, and respiration rate, *Kim fails to correlate the reduction in leaf length, plant height, chlorophyll content, protein content, stomatal frequency, and respiration rate with elevated levels of antioxidant observed by the Applicants*. Applicants assert that the Examiner has not provided sufficient evidence to demonstrate that spraying immature, germinating tobacco seedlings with ABA, according to *Kim's* method, necessarily produces (1)

the elevation of antioxidant capacity within mature, non-germinating tobacco leaves of harvested plants; or (2) the reduction in TSNA's as recited in the preamble of Claim 1. Applicants submit that the Examiner's assertion that a skilled person in the art would recognize that ABA exposure at the germination stage would result in elevated levels of antioxidants in mature leaves of tobacco plants or the reduction in TSNA's is mere speculation. Because a *prima facie* case of anticipation has not been established, either inherently or explicitly, Applicants respectfully request the withdrawal of the rejection of Claims 1, 2, 7-10, 12 and 20, and request the allowance of these claims.

Claim Rejections Under 35 U.S.C. § 103

MPEP §2143 provides that to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure." (MPEP sec. 2143 quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

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Claims 13, 15, and 16 stand rejected under 35 U.S.C. §103(a) in view of *Kim* (see pages 5-6 of Office Action).

Applicants traverse and assert that a *prima facie* case of obviousness has not been established. Applicants assert that *Kim* does not disclose the combination of steps recited in independent Claim 1, as discussed in arguments presented above to

traverse the anticipation rejections. Because a *prima facie* case of obviousness has not been established, Applicants respectfully request the withdrawal of the rejection of Claims 13, 15 and 16 (which depend on Claim 1), and request the allowance of these claims.

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Claims 14, 17 (now canceled), and 47 stand rejected under 35 U.S.C. § 103(a) in view of *Kim*. and further in view of *Agboma et al.* (Expl. Agric., vol. 33, pp. 345-352 (1997)) ("*Agboma*") and further in view of *Rensburg et al.* (Can. J. Bot., vol. 72, pp. 1535-1540 (1993)) ("*Rensburg*") (see pages 6-7 of Office Action).

Applicants traverse and assert that a *prima facie* case of obviousness has not been established. Applicants assert that *Kim* does not disclose the combination of steps recited in independent Claim 1, as discussed in arguments presented above to traverse the anticipation rejections. Furthermore, both *Agboma* and *Rensburg* fail to remedy the deficiencies of *Kim*. Thus, because *Kim*, *Agboma*, and *Rensburg* do not disclose the method recited in Claim 1, including "raising the levels of antioxidants in tobacco leaves by spraying a chemical solution onto the leaves of a growing tobacco plant at least one time prior to harvesting at about 1-3 weeks prior to harvesting, the antioxidants being raised at least 25 % compared to harvested tobacco plants grown without being sprayed with the chemical solution," a *prima facie* case of obviousness has not been established. Thus, Applicants respectfully request the withdrawal of the rejection of Claims 14 and 47 (which depend on Claim 1), and request the allowance of these claims.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.


In the event that there are any questions concerning this amendment, or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of present application may be expedited.

Respectfully submitted,

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